UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,193	08/26/2003	Marilyn H. Perrin	SALK1740-10 (088802-3218)	5260

30542 7590 05/01/2006

FOLEY & LARDNER LLP
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

EXAMINER	
BORGEEST, CHRISTINA M	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,193	PERRIN ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-11; 13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I and SEQ ID NOs: 14/15 in the reply filed on 10 March 2006 is acknowledged. The traversal is on the ground(s) that Group I claims (directed to a protein and the Group claims (directed to an antibody), could readily be searched in a single application because a search of the antibody would by necessity encompass a search of the protein. Furthermore, Applicants argue that the subject matter each of these groups is classified in the same class/subclass, and that each relate to the same receptor - CRF polypeptide.

This is not found persuasive because biotech applications are searched heavily in the non-patent literature, which is not classified thus classification does not help in this type of search, and a search of the antibody would not necessarily encompass the protein consisting of SEQ ID NO. 15.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11 and 13-19 are pending and under examination to the extent that they read on SEQ ID NOs: 14/15.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied

with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [120] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application No. 08/483,139 (CIP), 08/353,537 (CIP) and 08/079,320 (CIP) fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The above name applications do not provide support for SEQ ID NOs: 14 or 15. Thus those claims that make reference to SEQ ID NOs: 14 or 15 are given benefit of the date of the parent, 09/191,724, 12 November 1998. Applicants have elected SEQ ID NOs: 14 and 15, thus for the purposes of prior art, the following claims have an effective filing date of 12 November 1998: 1-11, 13-19.

Claim Objections

Claims 1-11 and 13-19 are objected to because of the following informalities: The claims recite non-elected species SEQ ID NOs: 5, 6, 7, 8, 9 10. Appropriate correction is required.

Information Disclosure Statement

The information disclosure statement filed 12 November 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it includes 2 pages from a previous 892 form cited in a previous case and the references are not in proper form to be considered. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, and claims 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, which depend from 1, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "suitable stringency" which is indefinite, because it does not define clearly the hybridization and wash conditions required, thus leaves open the identity of the nucleic acid sequences that would hybridize to the complement of SEQ ID NO: 14. See MPEP 2173:

> The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.

Neither the specification nor the art provides an unambiguous definition for "suitable stringency", therefore, the metes and bounds of the claimed invention cannot be determined.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-6, 8-11, 13-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the clamed inventions wherein the recited isolated protein comprises SEQ ID NO: 15 or an antigenic fragment thereof, does not enable the claimed invention broadly reciting variants and immunogenic fragments of SEQ ID NO: 15. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." (See

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 Fed. Cir. 1988) These factors include, but are not limited to: (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The claims are very broad; the variants as claimed read on a huge group of polypeptides. For instance, Claims 1-6, 8-10 and 15-19 claim the protein in terms of being encoded by polynucleotides that hybridize under suitable stringency to the complement of SEQ ID NO: 14. Although hybridization and wash conditions are recited, the use of the open language, "comprising", allows for the rehybridization and washing at lower stringency, thus many more polynucleotides than those that are complements of SEQ ID NO: 14 could potentially hybridize to SEQ ID NO: 14. Furthermore, the state of the art teaches that the temperature and salt concentrations at which hybridization is performed directly affects the results obtained. The conditions can be adjusted so the hybridzation is to a nucleic acid that has a lower degree of homology to the probe. See the website found at North Dakota State University, with regards to nucleic acid hybridization (ndsu.nodak.edu/instruct/mcclean/plsc731/dna/dna6.htm—accessed 7 April 2006). This also means that there is a degree of unpredictability as to what will hybridize to the complement of SEQ ID NO: 14, if the hybridization conditions are left open, as is the case in the claims.

In addition, the "immunogenic fragment" recited in claim 11 reads on any fragment of the protein, including a peptide consisting of 3-5 amino acids that is capable of inducing a general immune response. In the absence of any structural or functional limitations, the claim reads on any fragment of a G protein-coupled CRF receptor protein, and there are a huge number of polypeptides that would meet these criteria. The Applicants have provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, what polynucleotides would hybridize to SEQ ID NO: 14 and the immunogenic fragments that are encompassed in the claim. There is not adequate guidance as to the nature of immunogenic fragments.

The claims amount to single means claims. Single means claims are those that cover every conceivable means for achieving the stated purpose. Single means claims are nonenabling for the scope of the claim because the specification discloses at most only those means known to the inventor, in this case, a protein that is encoded by a polynucleotide consisting of SEQ ID NO: 14. When claims depend on a recited property, i.e., the ability of a polynucleotide to hybridize under any conditions to the complement of a recited sequence, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See MPEP 2164.08(a).

Due to the large quantity of experimentation necessary to generate the vast number of variants and immunogenic fragments of SEQ ID NO: 15 as recited in the

claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of changing hybridization conditions (see discussion above and recited reference) and the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 15, 16, 17, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Laurent et al. (FEBS, 1993; 335: 1-5). Laurent et al. teach a membrane bound G protein coupled receptor that consists of the SEQ ID 15 and is encoded by the polynucleotide consisting of SEQ ID NO: 14. Because the exact sequence of SEQ ID NO: 15 (claims 7, 10—see entire document, for instance, p. 2, Figure 1) is disclosed in this reference, the limitations of claims 1, 11, 15-19 (the protein is encoded by DNA that hybridizes to the complement of SEQ ID NO:

14), 2 (having sufficient binding affinity for CRF such that concentrations of 10 nanomolar CRF occupy greater than or equal to 50% of binding sites...), 3-6 (encoded by DNA having at least 60/70/80/90% nucleic acid identity to the reference polynucleotide sequences), 9, 16, 18 (product by process claims; a product disclosed in the prior art, made by a different process, does not render the claims patentable) are met by Laurent et al., thus the claims do not contribute anything new over the prior art.

Claims 1, 8 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (Proc Natl Acad Sci. 1993; 90: 8967-8971—on IDS filed 12 November 2003). Chen et al. teach an isolated G protein-coupled corticotrophin releasing factor receptor that consists of the SEQ ID 15 and is encoded by the polynucleotide consisting of SEQ ID NO: 14. Because the exact sequence of SEQ ID NO: 15 is disclosed in this reference (see, for instance, Figure 2), the limitations of claims 1 and 13 (the protein is encoded by DNA that hybridizes to the complement of SEQ ID NO: 14) are met. In addition, Chen et al. teach a radioreceptor assay of the cloned receptor (see p 8967 under Materials and Methods, right column, 5th paragraph), and a polypeptide according to claim 13 in which a cysteine is attached by a peptide bond to the carboxyl terminus of said polypeptide (p. 8969, Figure 2), thus the claims do not contribute anything new over the prior art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

Christina Borgeest, Ph.D.

ELIZABETH KEMMERER
PRIMARY EXAMINER